REMARKS

Applicants appreciate the indication that formal drawings are approved and address the objection to the specification as follows. It is stated that sequences were discussed on pages 11, 15 and 16 not accompanied by sequence identifier numbers. However, in the submission filed in response to the Notice to Comply, filed 17 April 2002, the required sequence numbers were inserted. A copy of the response showing the insertion of these sequence numbers is enclosed for the convenience of the Office. In view of this previous submission, the objection to the specification may be withdrawn.

Applicants appreciate the withdrawal of the rejections previously made under 35 U.S.C. § 102(b). The sole remaining rejection is made under 35 U.S.C. § 112, paragraph 1. Although the rejection is framed in terms of lack of enablement, the true basis appears to be an asserted lack of utility. There appears to be no assertion that the applicants have not adequately described how to introduce a nucleic acid molecule into a mammalian subject by transplanting into the dermis of said subject at least one hair follicle that has been modified *ex vivo* to contain the nucleic acid molecule. Accordingly, it is assumed that the description of how to carry out the invention is considered adequate by the Office.

However, the Office asserts that the invention has no "real world" utility. The basis for this appears to be the assertion that there is no value in inserting nucleic acids into tissues. The basis for this, in turn, appears to be that gene therapy is in its early stages and that although it is clear that it might be desirable to introduce nucleic acids into mammalian subjects, and there are thousands of scientists engaged in this work, a contribution to the efforts of these scientists is inherently un-useful unless individuals are actually cured by such therapy.

Of course, there are a number of instances in which individuals have, in fact, benefited from "gene therapy" including the French children who have been spared from life in a bubble

chamber by virtue of this technique. It is recognized that such therapies are not routine and that unfortunate side effects have occurred; this does not mean that the entire field is forever doomed to failure or that contributions to this field are, therefore, un-useful. No field is ever trouble-free at the outset, and the Office would be hard pressed to find anyone who is of the view that the ability to supply individuals with nucleic acids will never be brought into routine use.

Analogies abound. Who would think, looking at the freeways of today, that the early purchasers of automobiles would have been addressed with "get a horse." The current problems with computer viruses and multiple system breakdowns have not discouraged the widespread development and continued improvement in computer technology. One cannot expect an entire new technology to be perfect upon its inception. Its eventual success depends on a multiplicity of contributions, *such as those of the invention*, ultimately, to provide the overall technology for success. These contributions, required in order to provide the basis for success, is itself an "immediate benefit to the public."

Contrary to the contention of the Office, the asserted utility does not amount simply to studying the properties of the claimed method or improving the invention. The invention is not gene therapy. Rather, the invention as described in Example 2 permits optimization of the claimed technique which is, itself, fully developed.

Respectfully, the position of the Office as reflected in the current rejection fails to comprehend the realities of the progress of technology. It is well-recognized that both gene therapy and generation of an immune response by *in situ* production of proteins are viable approaches to therapy and prophylaxis and will be as routine in the relatively near future as driving an automobile is today. Technologies of this sort involve the interplay of many factors, therefore their routinization requires the contribution of many techniques such as those set forth

in the present invention. To assume that these techniques are of no value to the public until the entire field becomes routine loses sight of the complexity of contemporary technology and science.

Accordingly, applicants believe the present claims are in a position for allowance and passage of these claims to issue is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 312762002400.

Respectfully submitted,

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